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AMENDMENTS TO THE SPECIFICATIONRECEIVED
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page 8, lines 7-24:

- Current screening tests for disorders of glucose metabolism are sub-optimal.
- 5 Screening tests often uses glucose determinations at a few select time periods such as during fasting or two hours postprandial. These discrete tests often fail to diagnose diabetes, IGT, or even insulin resistance syndrome. People with insulin resistance syndrome are able to produce enough insulin to maintain non-diabetic glucose levels, but are still at significant risk for heart attack or stroke.
- 10 Two glucose tolerance test profiles are presented in Figure 1. The first subject glucose profile 101 has a 2-hour glucose concentration of 134 mg/dL, respectively. Under the current American Association of Clinical Endocrinologists (AACE) guideline for the 120-minute post-glucose challenge this subject is not classified as being diabetic, having IGT, or having insulin
- 15 resistance syndrome despite having a peak glucose concentration of 210 mg/dL [<http://www.aace.com/pub/BMI/findings.php>]. Similarly, the second subject glucose profile 102 has a 2-hour concentration of 127 mg/dL. Again this subject fails the AACE guideline for even Insulin resistance syndrome despite having apparent IGT based upon the peak glucose concentration of 178 mg/dL. Fasting
- 20 plasma glucose levels have also been reported to fail to identify 90% of IGT and 62% of diabetes cases [Constantine Tsigo *et. al.* Poster 880-P, ADA 61st Scientific Sessions, PA, June 22-26, 2001].

page 3, lines 12-17:

- 25 According to the American Diabetes Association, Gestational diabetes mellitus (GDM) is defined as glucose intolerance with onset or first recognition during pregnancy, whether or not the condition persists after pregnancy. It does not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy [See
- 30 http://care.diabetesjournals.org/cgi/content/full/25/suppl_1/s94].

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page 6, lines 3-7:

Diabetes and impaired glucose tolerance have been called "silent killers" because many people are unaware that they have the disease until they develop one of its life-threatening complications. Complications of diabetes include retinopathy, neuropathy, and cardiovascular problems

5 [http://www.diabetes.org:80/main/application/commercewf?origin=*.jsp&event=link(B1)].

page 7, lines 29-32:

10 Fetal Complications: Infants of gestationally diabetic mothers are at higher risk of fetal anomalies, e.g. birth defects, macrosomia, higher birth weights, post-partum hypoglycemia, and respiratory distress syndrome

[http://www.diabetes.org:80/main/application/commercewf?origin=*.jsp&event=link(B1)].

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